

IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

1. (currently amended) A pharmaceutical gastro-retentive delivery system for controlled release of a therapeutically active agent in the stomach or upper part of the gastro[[-]] intestinal tract in the form of a bilayer dosage form which comprises,
 - a) a first layer (layer-A) which is responsible for retaining the dosage form in the stomach or upper part of the gastro[[-]]intestinal tract (spatial control) for a prolonged period, comprising [[of]] pharmaceutical excipients having low bulk density, which is selected from a mixture consisting of
 - (i) polymers selected from the group consisting of ethylcellulose or suitable enteric polymers of cellulose derivatives and
 - (ii) hydrogenated oils, waxes, fatty acids either alone or in combination; optionally with other pharmaceutical aids; and
 - b) a second layer (Layer- B) which is responsible for prolonged or controlled drug delivery (temporal control) of the therapeutically active agent, ~~which comprises of comprising~~ the therapeutically active agent and controlled release matrix polymers optionally with other pharmaceutical aids.
2. (currently amended) The delivery system as claimed in claim 1, wherein said pharmaceutical excipient with low bulk density is ethyl cellulose in combination with hydrogenated oils.
3. (currently amended) The delivery system as claimed in claim 1, wherein the ratio of ethylcellulose and hydrogenated oils is ~~in the range of from~~ 95:5 to 30:70.
4. (currently amended) The delivery system as claimed in claim 1, wherein said pharmaceutical aids are selected from the group consisting of pharmaceutical lubricants, antiadherents, and glidants.

5. (currently amended) The delivery system as claimed in claim [[4]] 1, wherein said pharmaceutical aids are selected from the group consisting of magnesium stearate, talc, colloidal silicon dioxide, stearic acid, magnesium stearate ~~fumarate-fumerate~~, glyceryl behenate, and hydrogenated oils or a combination thereof.

6. (currently amended) The delivery system as claimed in claim 1, wherein said controlled release matrix polymers is selected from the group consisting of ~~synthetic or semisynthetic cellulose derivatives like~~ hydroxypropyl methylcellulose, ethylcellulose, hydroxypropylcellulose, methylcellulose, sodium carboxymethylcellulose, ~~natural polymers such as~~ xanthan gum, gelatin, synthetic polymers, acrylic acid derivatives, and polyvinyl acetate or a mixture[[s]] thereof.

7. (currently amended) The delivery system as claimed in claim 1, wherein said pharmaceutical aids are selected from the group consisting of pharmaceutical fillers, disintegrants, lubricants, binders, antiadherents, and glidants or a combination[[s]] thereof.

8. (currently amended) The delivery system as claimed in claim [[7]] 1, wherein said, pharmaceutical aids ~~disintegrants~~ are selected from the group consisting of crosslinked polyvinyl pyrrolidone, crosslinked sodium carboxymethyl cellulose, sodium starch glycolate, microcrystalline cellulose, starch, and pregelatinized starch or a ~~their~~ combination[[s]] thereof.

9. (currently amended) The delivery system as claimed in claim [[7]] 1, wherein said pharmaceutical aids ~~binders~~ are selected from ~~natural polymers selected from~~ the group consisting of starch, ~~or gum including~~ acacia gum, tragacanth gum, and gelatin or synthetic polymers selected from the group consisting of polyvinyl pyrrolidone, methyl cellulose, ethyl cellulose, hydroxypropyl methylcellulose, sodium carboxymethylcellulose, and hydroxypropyl cellulose.

10. (currently amended) The delivery system as claimed in claim [[7]] 1, wherein said pharmaceutical ~~aids antiadherents, glidants, and lubricants~~ are selected from the group consisting of magnesium stearate, talc, colloidal silicon dioxide, stearic acid, salts of stearic acid, magnesium stearate fumarate, glyceryl behenate, and hydrogenated oils.

11. (original) The delivery system as claimed in claim 1, wherein said therapeutically active agent is in the form of a raw powder, dispersed or embedded in a suitable liquid, semisolid, micro- or nanoparticles, micro- or nanospheres, a tablet, a caplet, or in a suitable processable form.

12. (original) The delivery system as claimed in claim 1, wherein said therapeutically active agent is a drug having a narrow absorption window in the gastrointestinal tract.

13. (original) The delivery system as claimed in claim 1, wherein said therapeutically active agent is selected from the group consisting of therapeutic, chemotherapeutic, antibiotic antidiabetic, anti-cancers, anti-fungals, anti-filarial, antiviral agents, lipid lowering agents, analgesics, non-steroidal anti-inflammatory agents, anti-ulcer agents, anti-epileptics, anti-gout, immunosuppressants, drugs for respiratory therapy, dopaminergic agents, skeletal muscle relaxants, cardiovascular agents, antipsychotics or those drugs which does not show uniform absorption characteristic throughout the length of the gastrointestinal tract.

14. (currently amended) The delivery system as claimed in claim 1, wherein said therapeutically active agent is ~~may also be~~ a drug for local treatment of the gastrointestinal tract.

15. (original) The delivery system as claimed in claim 1, wherein said therapeutically active agent is selected from antibacterial/anti-infective agents, such as ofloxacin, ciprofloxacin, cefuroxime, cefatrizine, cefpodoxime, clarithromycin, loracarbef, azithromycin, cefadroxil, cefixime, amoxycillin; antivirals, such as acyclovir;

cardiovascular agents, such as diltiazem, captopril; lipid lowering agents such as simvastatin, lovastatin, atorvastatin; non-steroidal anti-inflammatory agents such as etodolac, ketorolac; anti-ulcer agents such as ranitidine, famotidine; drugs for respiratory diseases, such as fexofenadine, pseudoephedrine, phenylpropanolamine, dextromethorphan, chlorpheniramine; dopaminergic agents, such as bromocriptine; immunosuppressants, such as cyclosporin; skeletal muscle relaxants, such as baclofen; anti-gout agents, such as allopurinol; antidiabetic agents such as acarbose, glipizide.

16. (currently amended) A method of using ~~Use of~~ the delivery system as claimed in claim 1, for treatment of disease conditions, the method comprising orally administering the bilayer dosage form to a human patient ~~as described in any preceding claims above.~~

17. (currently amended) The delivery system as claimed in claim 1, wherein the layers A and [[&]] B are prepared by ~~technique selected from~~ melt granulation, wet granulation, or direct compression.

18. (currently amended) The delivery system as claimed in claim 1, wherein the amount of therapeutically active agent is present in an amount ranging from about 0.2 to 1000 mg.

19. (currently amended) The delivery system as claimed in 1, wherein the dosage form floats on the surface of the gastric fluid for prolonged period ~~ranging from~~ 0.5 to 10 hours.

20. (currently amended) The delivery system as claimed in claim 1 which is ~~optionally~~ coated with a rapidly dissolving water soluble film forming polymer or rapidly dissolving pharmaceutical excipient.

21. (currently amended) The [[A]] drug delivery system as claimed in claim 1 which is in the form of ~~includes~~ tablets, caplets, or tablets filled in capsules.

22. (original) A pharmaceutical composition prepared according to the present invention suitable for human administration.